ETHYLENEAMINES PRODUCT STEWARDSHIP DISCUSSION GROUP
AEEA TESTING CONSORTIUM

8EHQ-0404-15167

April 20, 2004

MR 274882

Via Certified Mail
Return Receipt Number 7003 2260 0001 8137 3139

TSCA Section 8(e) Coordinator
Document Control Officer (MC-7407)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

8EHQ-02-15187

04 APR 26 AM 11:24

RECEIVED

Re: Toxic Substances Control Act -- Section 8(e)

Dear TSCA Section 8(e) Coordinator:

The Ethyleneamines Product Stewardship Discussion Group (EPSDG) Aminoethylethanolamine (AEEA) Testing Consortium, c/o Mr. William C. Hayes, c/o Bergeson & Campbell, P.C., 1203 Nineteenth Street, N.W., Suite 300, Washington, DC 20036-2401, submits to the U.S. Environmental Protection Agency (EPA), pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA), interim results of a probe study with AEEA (CAS No. 111-41-1).[1] The EPSDG AEEA Testing Consortium is comprised of the following companies: Akzo-Nobel Functional Chemicals, LLC, BASF Corporation, The Dow Chemical Company, and Huntsman Corporation. The study was performed by BASF Aktiengesellschaft, Ludwigshafen, Germany.

2004 APR 30 PM 2:33

RECEIVED
OPPT NCIC

[1] On July 3, 2002, the EPSDG submitted a notice pursuant to TSCA Section 8(e) for an Organization for Economic Cooperation and Development (OECD) 421 Reproduction/Developmental Toxicity Screening Test in Wistar rats (strain CrlGlxBrlHan:WI) with AEEA. On October 28, 2003, the EPSDG AEEA Testing Consortium submitted a TSCA Section 8(e) notice regarding a histopathology study that was a follow-up study to the OECD 421 study. The probe study that is the subject of this notice is another follow-up study to the OECD 421 study.

The Dow Chemical Company • Mr. William C. Hayes • 1691 N. Swede Road • Midland, Michigan 48674
Huntsman Ethyleneamines, Ltd. • Mr. Michael O. Nutt • 7114 North Lamar Boulevard • Austin, Texas 78752
Akzo Nobel Functional Chemicals LLC • Mr. Mark R. Schroeder • 5 Livingstone Ave • Dobbs Ferry, NY 10522
BASF Corporation • Ms. Patricia A. Cruse • 3000 Continental Drive • Mt. Olive, New Jersey 07828
BASF Agktingesellschaft • Roland Rossbacher, Ph.D. • Carl-Bosch-Strasse 38 • Ludwigshafen • Rheinland-Pfalz, D-67056, Germany

8904000001 40

This information is being submitted, as required under TSCA Section 8(e), within 30 calendar days after the date this information was obtained. A summary describing the nature of the adverse effects being reported is provided below.

- **Methods**: The study was carried out to gather information on the optimal conditions of treatment for examining malformations of the major pericardial blood vessels as observed in an earlier conducted OECD 421 study. There are no guidelines for this special study. The test substance was administered as an aqueous solution by oral gavage to seven presumed pregnant female rats per group at doses of 0, 5, and 50 mg/kg-bw from gestation day six through to day four post-delivery. On postnatal day four, litters were standardized to eight offspring, which were then divided into four subgroups. Subgroup IA pups were administered the same dosing solution as the dam from postnatal day 14 through to postnatal day 28, when they underwent necropsy. Subgroup IB pups remained untreated to postnatal day 28, when they underwent necropsy as a control group for subgroup IA. Subgroup IIA pups were administered the same dosing solution as the dam from postnatal day 14 through to postnatal day 60, when they underwent necropsy. Subgroup IIB pups were administered the same dosing solution as the dam from postnatal day 14 through to postnatal day 28, and then remained untreated to postnatal day 60, when they underwent necropsy as a control group for subgroup IIA. Developmental toxicity was assessed through a macroscopic examination of post-delivery day four pups, post-delivery day 28 pups, and post-delivery day 60 offspring, with particular attention being paid on the major pericardial blood vessels. All offspring were preserved for possible histopathologic processing and examination.

- **Results**: No clinical observations were noted in the dams. At necropsy, 6/20 offspring from subgroup IA and 2/20 from subgroup IIA showed dilation of the aorta, while 3/20 offspring from subgroup IIB showed either dilation of the aorta or thickening of the aorta wall. Pups culled at postnatal day four and those from subgroup IIB showed no adverse effects. Two out of 11 test substance-treated post-delivery day four pups showed alterations of the major pericardial blood vessels, such as aneurysm of aortic arch or media hyperplasia of abdominal aorta. Two out of ten pups from subgroup IA showed alterations of the major

pericardial blood vessels, such as irregular and delicate elastin fibres. Two out of eight pups from subgroup IIA and three out of five from subgroup IIB showed irregular and delicate elastin fibres in the aortic arch.

If you have any questions, please contact Lynn Bergeson at (202) 557-3801 or lbergeson@lawbc.com.

Sincerely,

William C. Hayes

William C. Hayes, Chair
EPSDG AEEA Testing Consortium

cc: EPSDG AEEA Testing Consortium (via e-mail)